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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/730,559	12/07/2000	Tetsuyoshi Ishiwata	766.21 CIP	9523

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/730,559	ISHIWATA ET AL.	
	Examiner	Art Unit	
	Joseph T. Voitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,10-13 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 4,6 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 10-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/7/2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

This application, filed December 7, 2000, is a continuation in part of application 09/090,672, filed June 4, 1998, which is a continuation in part of PCT/JP97/04468, filed December 5, 1997.

Claims 2, 5, 7-9, 14-21 have been canceled. Claim 22 has been added. Claims 1, 3, 4, 6, 10-13 and 22 are pending.

Election/Restriction

Applicant's election with traverse of Group 7, SEQ ID NO: 7, made on January 20, 2004 was acknowledged. No further arguments have been provided therefore, the requirement is still deemed proper.

Newly added claim 22 is a method similar to that of claim 4, and would be included in this non-elected group.

Claims 1, 3, 4, 6, 10-13 and 22 are pending. Claims 4, 6 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement. Claims 1, 3, 10-13 are currently under examination as they are drawn to a DNA related to IgA nephropathy as set forth in SEQ ID NO: 7 .

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on December 5, 1996. However, Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

More importantly, Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). Specifically, the present application is a CIP of 09/090,672 and

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a comparison of the disclosures indicates that the present disclosure is the first presentation of the specific sequence set forth as SEQ ID NO: 7 (compare for example '672 Table 2, page 59 with Table 2, page 75 in the instant application). It is noted that clones designated as INM063-7 was presented, however this does not provide the specific support for SEQ ID NO: 7 currently under examination. Accordingly, the claims presently under examination are given the priority date as of the filing date of the instant application.

Applicants have not addressed the arguments or provided evidence regarding the claim for priority as it encompasses SEQ ID NO: 7 as discussed above. Accordingly, the instant application and the claims presently under examination are given the priority date of as of the filing date of the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the metes and bounds of claims 1, 3, 10 and 13 are unclear and indefinite in the recitation of "represented by" because it is a relative term subject what one would think is representative. Neither the claims nor the specification clearly set forth structural or functional requirements of what is 'representative' of SEQ ID NO: 7. Dependent claims are also rejected because they do not clarify the basis of the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, and 10 stand rejected under 35 U.S.C. 102(b) as being anticipated by Rouault *et al.*

Claims 1 and 3 stand rejected under 35 U.S.C. 102(b) as being anticipated by Genbank entry M58511.

Claims 1, 3 and 10-13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Samaniego *et al.*

Applicants note the amendments to the claims and argue that the claims no longer encompass the sequences taught by the cited references. Applicants provide a comparison of the homology between the sequences noting that the prior art does not teach all the sequence set forth in SEQ ID NO: 7. See Applicants amendment, pages 6-7 and homology searches in Tabs A and B. Applicants' arguments have been fully considered, but not found persuasive.

The amendments to the claims are noted, however the new language "represented by" is broad and can reasonably be interpreted to encompass sequences other than specifically set forth as SEQ ID NO: 7. As discussed above in the rejection made under 35 USC 112, second paragraph, representation is subjective and dependent on various interpretations of what is represented. The differences between the sequences in the prior art and that of SEQ ID NO: 7 are noted (as set forth in Tabs A and B), however as supported by this evidence the relatedness

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of SEQ ID NO: 7 and that of the art indicates that SEQ ID NO: 7 could at some level represent these sequences as highly homologous sequences or representative of alleles.

Briefly, as set forth previously, Rouault *et al.* teach a polynucleotide sequence that encodes the human IRP2 protein. Sequence homology searches confirm the teaching in the present disclosure that SEQ ID NO: 7 is related to IRP2. M58511 is a polynucleotide sequence that encodes the human IRP2 protein. Sequence homology searches confirm the teaching in the present disclosure that SEQ ID NO: 7 is related to IRP2. Samaniego *et al.* teach a polynucleotide sequence that encodes the human IRP2 protein. Sequence homology searches confirm the teaching in the present disclosure that SEQ ID NO: 7 is related to IRP2. Finally, Samaniego *et al.* teach a method where the sequences are used to generate an IRP2 protein by expressing and purifying the protein from a cell culture.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

Joe Woitach
AUG 32